# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

WYETH,	)
Plaintiff,	)
v.	) C. A. No. 06-222 (JJF)
IMPAX LABORATORIES, INC.,	)
Defendant.	)

# DECLARATION OF KAREN JACOBS LOUDEN, ESQ.

- I, Karen Jacobs Louden, Esq., hereby declare as follows:
- 1. I am a partner with the law firm of Morris, Nichols, Arsht & Tunnell, L.L.P. I am one of the attorneys representing Wyeth in the current litigation.
- 2. Attached hereto as Exhibit 1 is a true and correct copy of Defendant Impax Laboratories, Inc.'s Responses To Plaintiff's First Request For The Production of Documents And Things (Nos. 1-87).
- 3. Attached hereto as Exhibit 2 is a true and correct copy of an August 4, 2006 letter from Linda A. Wadler to Jessica R. Wolff.
- 4. Attached hereto as Exhibit 3 is a true and correct copy of an August 21, 2006 letter from Samuel F. Ernst to Linda A. Wadler.
- 5. Attached hereto as Exhibit 4 is a true and correct copy of a September 7, 2006 letter from Linda A. Wadler to Samuel F. Ernst.
- 6. Attached hereto as Exhibit 5 is a true and correct copy of a September 11, 2006 letter from Linda A. Wadler to Jessica R. Wolff.

7. Attached hereto as Exhibit 6 is a true and correct copy of a September 13, 2006 letter from Jessica R. Wolff to Linda A. Wadler.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed on this 18th day of September, 2006.

Karen Jacobs Louden (#2881)

537285

# **CERTIFICATE OF SERVICE**

I, Karen Jacobs Louden, hereby certify that on September 18, 2006, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer MORRIS, JAMES, HITCHENS & WILLIAMS, LLP

I also certify that copies were caused to be served on September 18, 2006 upon the following in the manner indicated:

# **BY HAND**

Mary B. Matterer Morris, James, Hitchens & Williams 222 Delaware Avenue P.O. Box 2306 Wilmington, DE 19899

# BY FEDERAL EXPRESS

M. Patricia Thayer John M. Benassi Jessica R. Wolf Heller Ehrman LLP 4350 La Jolla Village Drive San Diego, CA 92102

> /s/ Karen Jacobs Louden klouden@mnat.com

# EXHIBIT 1

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

v.  IMPAX LABORATORIES, INC.,  Defendant.	) ) )
WYETH, Plaintiff,	) ) ) Civil Action No.: 06-222 JJF

# **DEFENDANT IMPAX LABORATORIES, INC.'S RESPONSES TO** PLAINTIFF'S FIRST REQUEST FOR THE PRODUCTION OF **DOCUMENTS AND THINGS (NOS. 1-87)**

Pursuant to Federal Rule of Civil Procedure 34, Defendant Impax Laboratories. Inc. ("Impax") responds to requests for production of Plaintiff Wyeth ("Wyeth") as follows:

#### **GENERAL OBJECTIONS**

The following general objections apply to each and every request for production propounded by Wyeth and said general objections are incorporated into each of the following specific responses by reference as if set forth in full therein.

- Impax objects to Wyeth's "Instructions" and "Definitions," and to each and every request for production to the extent they seek to impose obligations and demands on Impax beyond those contemplated by Federal Rules of Civil Procedure 26 and 34, and the applicable Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware ("Local Rules").
- 2. Impax objects to the production of electronic documents until the parties have come to an agreement or the Court has ruled as to the parties' obligations with

respect to the format and content of such productions, in accordance with the amendments to the Federal Rules of Civil Procedure that will take affect during the pendency of this action and will govern production of documents and things therein.

- 3. Impax objects to Wyeth's definition of the term "venlafaxine product" as overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Impax will limit documents and things produced in response to the requests using this term to the products that are the subject of ANDA 78-057, EFFEXOR® ("Effexor"), and EFFEXOR XR® ("Effexor XR") as appropriate given the context in which it is used.
- 4. Impax objects to Wyeth's definition of the term "Impax" as overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Impax will limit documents and things produced in response to the requests using this term using this term to entities under Impax's control that possess documents regarding the subject of ANDA 78-057.
- Impax objects to Wyeth's definition of the term "Wyeth" as overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Impax will limit documents and things produced in response to the requests using this term to entities that Impax is informed and believes are under Wyeth's control.
- 6. Impax objects to each and every request for production to the extent it calls for documents or things that are protected by the attorney-client privilege, the attorney work-product doctrine, or any other applicable privilege or immunity.
- 7. Impax objects to Wyeth's instruction that seeks information regarding documents and things that have been lost, discarded, destroyed, or are otherwise not available for production, as overly broad, unduly burdensome, oppressive, not reasonably calculated to lead to the discovery of admissible evidence, and because it imposes

obligations and demands on Impax beyond those contemplated by Federal Rules of Civil

Procedure 26 and 34, and the Local Rules.

- 8. Impax objects to each and every request for production to the extent it seeks responses that involve the disclosure of information, documents and/or things that would invade its privacy rights or the privacy rights of other nonparties to this action, such as Impax's employees.
- 9. Impax objects to each and every request for production to the extent it is overly broad, unduly burdensome, or oppressive.
- 10. Impax objects to each and every request for production to the extent it is vague and ambiguous.
- 11. Impax objects to each and every request for production to the extent it calls for legal conclusions in order to produce documents or things.
- 12. Impax objects to each and every request for production to the extent it calls for documents or things that are neither relevant to the subject matter of this action nor reasonably calculated to lead to the discovery of admissible evidence because, *inter alia*, all allegations by Wyeth concerning willfulness have been withdrawn.
- 13. Any response provided herein stating that documents and things will be produced is to be construed as referring only to responsive documents and things that are not otherwise subject to the general objections above or any specific objection noted below. Moreover, such statement with respect to a request is not a representation that any such documents or things exist, but only that a reasonably diligent search will take place and if that search discovers responsive, non-privileged documents or things, Impax will produce such documents and things. Impax may supplement or otherwise amend its responses pursuant to Federal Rule of Civil Procedure 26(e).
- 14. Until the entry of a suitable protective order in this action, all documents and things produced by Impax, whether in response to these requests, in response to other

requests, or by agreement of the parties, shall be deemed confidential pursuant to Local Rule 26.2 and treated accordingly by Wyeth and its counsel.

#### SPECIFIC OBJECTIONS AND RESPONSES

Subject to the above general objections, and without waiving the same, Impax responds to specific requests for production as follows:

#### **REQUEST FOR PRODUCTION NO. 1:**

Documents and things sufficient to show the design, composition (including ingredients by name and weight percent), structure, and mechanism of operation in the human body of the Impax Venlafaxine HCl Extended-Release Capsules.

## **RESPONSE TO REQUEST FOR PRODUCTION NO. 1:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 2:**

A complete copy of ANDA 78-057, including but not limited to all amendments, supplemental filings, or additions, without restriction as to date.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 2:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Subject to and without waiving the foregoing objections, Impax will produce a complete copy of ANDA 78-057, and all supplemental or additional filings with respect thereto, submitted to the FDA.

#### **REOUEST FOR PRODUCTION NO. 3:**

A complete copy of the following sections of ANDA 78-057, including but not limited to all amendments, supplemental filings, or additions, without restriction as to date:

- (a) Cover letter,
- (b) Table of Contents,
- (c) Patent Certification and Exclusivity Statement,
- (d) Comparison: Generic Drug vs. Reference Listed Drug,
- (e) Labeling and Labeling Comparison,
- (f) Bioavailability/Bioequivalence,
- (g) Components and Composition Statements,
- (h) Manufacturing and Processing Instructions,
- (i) In-Process Controls,
- (j) Controls for the Finished Dosage Form,
- (k) Executed Form 356(h),
- (I) Raw Material Controls,
- (m) Field Copy Certification and Authorization Letters,
- (n) Analytic Methods, and
- (o) Description of Manufacturing Facilities.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 3:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Subject to and without waiving the foregoing objections, Impax will produce a complete copy of ANDA 78-057, and all supplemental or additional filings with respect thereto, submitted to the FDA.

#### **REQUEST FOR PRODUCTION NO. 4:**

One hundred (100) samples of each venlafaxine product that Impax intends to market if ANDA 78-057 is approved by the FDA.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 4:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 5:**

All documents concerning the research and development done by or on behalf of Impax that resulted in each product that is the subject of ANDA 78-057.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 5:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is vague and ambiguous by its use of the term "that resulted in". Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### REQUEST FOR PRODUCTION NO. 6:

All documents concerning in vitro dissolution testing generated in connection with the research and development that resulted in the Impax Venlafaxine HCl Extended-Release Capsules.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 6:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "in vitro dissolution testing" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### REQUEST FOR PRODUCTION NO. 7:

All documents concerning any in vitro dissolution testing of EFFEXOR® XR. RESPONSE TO REQUEST FOR PRODUCTION NO. 7:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "in vitro dissolution testing" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### REQUEST FOR PRODUCTION NO. 8:

All documents concerning any comparison of in vitro dissolution testing of EFFEXOR® XR and any other venlafaxine product.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 8:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "in vitro dissolution testing" as vague and ambiguous. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### REQUEST FOR PRODUCTION NO. 9:

All documents concerning any in vitro dissolution testing of any venlafaxine product.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 9:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "in vitro dissolution testing" as vague and ambiguous. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 10:**

All laboratory notebooks generated in connection with the research and development that resulted in the Impax Venlafaxine HCl Extended-Release Capsule. **RESPONSE TO REQUEST FOR PRODUCTION NO. 10:** 

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged pages of laboratory notebooks generated in connection with the research and development that resulted in the Impax Venlafaxine HCl Extended-Release Capsule, as specifically defined.

#### **REQUEST FOR PRODUCTION NO. 11:**

All documents concerning nausea, vomiting and any other side effect associated with the administration of any immediate release venlafaxine product.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 11:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "immediate release" as vague and ambiguous. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057, Effexor, and Effexor XR. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and

without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 12:**

All testing and/or analysis of EFFEXOR® XR conducted by or on behalf of Impax.

## RESPONSE TO REQUEST FOR PRODUCTION NO. 12:

Impax objects to this request on the grounds set forth in the General Objections. incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 13:**

All patents and/or patent applications concerning any extended release or an immediate release venlafaxine product in which Impax has any ownership rights.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 13:**

Impax objects to this request on the grounds set forth in the General Objections. incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "extended release" and "immediate release" as vague and ambiguous. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 14:**

All documents and things concerning ANDA 78-057.

## **RESPONSE TO REQUEST FOR PRODUCTION NO. 14:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REOUEST FOR PRODUCTION NO. 15:**

All documents and things concerning the preparation and filing of ANDA 78-057. RESPONSE TO REQUEST FOR PRODUCTION NO. 15:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 16:**

All documents and things concerning any analysis, study, investigation, testing, or report prepared by or on behalf of Impax to provide data for ANDA 78-057.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 16:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "analysis", "study", "investigation", testing", and "report" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

## **REQUEST FOR PRODUCTION NO. 17:**

All documents and things concerning the materials and process used to manufacture the extended release venlafaxine products Impax seeks to market under ANDA 78-057.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 17:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "materials", "process used to manufacture", and "market" as vague and ambiguous. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

## **REQUEST FOR PRODUCTION NO. 18:**

All documents and things concerning Impax's plans for the commercial manufacture of any venlafaxine product, including but not limited to the products that are the subject of ANDA 78-057.

## **RESPONSE TO REQUEST FOR PRODUCTION NO. 18:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 19:**

All documents and things concerning all communications, contacts, submissions, or correspondence between Impax and the FDA concerning any Abbreviated New Drug Application for any extended release venlafaxine product.

## **RESPONSE TO REQUEST FOR PRODUCTION NO. 19:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not

reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

## **REQUEST FOR PRODUCTION NO. 20:**

All documents and things concerning all communications, contacts, submissions, or correspondence between Impax and the FDA concerning any New Drug Application for any extended release venlafaxine product.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 20:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to New Drug Applications for Effexor, and Effexor XR. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request,

## **REQUEST FOR PRODUCTION NO. 21:**

All documents and things concerning all communications, contacts, submissions, or correspondence between Impax and the FDA concerning ANDA 78-057.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 21:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to

the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 22:**

All documents and things concerning all FDA review letters concerning ANDA 78-057.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 22:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 23:**

All documents and things concerning Impax's decision to seek FDA approval for an extended release venlafaxine product.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 23:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and

without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 24:**

All documents and things concerning all communications, contacts, submissions, filings, and correspondence with the FDA by Impax concerning any extended release venlafaxine product.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 24:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057, Effexor, and Effexor XR. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce nonprivileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 25:**

All documents and things concerning Impax's decision to develop a generic version of EFFEXOR® XR.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 25:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "generic" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of

admissible evidence, and will limit its response to the products that are the subject of ANDA 78-057. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 26:**

All documents considered by Impax in connection with the decision to market an extended release venlafaxine product.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 26:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "market" as vague and ambiguous. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to the term "decision to market" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REOUEST FOR PRODUCTION NO. 27:**

All documents evidencing or reflecting the factors Impax considered in deciding to seek FDA approval to market an extended release venlafaxine product in the United States.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 27:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "market" as vague and ambiguous. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REOUEST FOR PRODUCTION NO. 28:**

All documents and things concerning Impax's decision to file ANDA 78-057, including, but not limited to, pharmaceutical, chemical and/or medical research concerning any venlafaxine product, all economic and marketing research, analyses, or reports concerning the sales or potential sales of any venlafaxine product, and all internal communications or records, notes of conferences, notes of interviews, and memoranda concerning the desirability of obtaining FDA approval for an extended release venlafaxine product.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 28:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REOUEST FOR PRODUCTION NO. 29:**

All documents and things concerning any communications or contacts between Impax and third parties concerning ANDA 78-057.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 29:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 30:**

All documents and things concerning any communications or contact between Impax and third parties concerning venlafaxine and/or an extended release venlafaxine product.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 30:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it seeks communications regarding venlafaxine as overly broad and not reasonably calculated to lead to the discovery of admissible evidence, and will limit documents and things produced in response to this request to products that are the subject of ANDA 78-057, Effexor, and Effexor XR. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

## **REQUEST FOR PRODUCTION NO. 31:**

All documents and things concerning or considered in the preparation of a letter by Impax dated February 21, 2006, informing Wyeth pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) of the filing of ANDA 78-057.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 31:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 32:**

All documents and things concerning the Patent Certification by Impax to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that Impax Venlafaxine HCl Extended-Release Capsules would not infringe claims of the '171, '120 and/or '958 patents including, but not limited to, all studies, reports, opinions, notes of conferences, notes of interviews, analyses of prior art, and/or analyses of those patents.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 32:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "studies", "reports", "opinions", "conferences", "interviews", and "analyses" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 33:**

All documents and things concerning the Patent Certification by Impax to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that claims of the '171, '120 and/or '958 patents are invalid or unenforceable, including, but not limited to, all studies, reports, opinions, notes of conferences, notes of interviews, analyses of prior art, and analyses of the '171, '120 and/or '958 patents.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 33:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "studies", "reports", "opinions", "conferences", "interviews", and "analyses" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 34:**

All documents and things forming the bases for, refuting, or concerning Impax's contention that the filing of ANDA 78-057 does not constitute infringement of the '171, '120, and/or '958 patents.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 34:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it calls for a legal conclusion in determining documents that are responsive to the request. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 35:**

All documents and things forming the bases for, refuting, or concerning, Impax's contention that the manufacture, use, or sale of Impax Venlafaxine HCl Extended-Release Capsules will not constitute infringement of the '171, '120 and/or '958 patents.

RESPONSE TO REQUEST FOR PRODUCTION NO. 35:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it calls for a legal conclusion in determining documents that are responsive to the request. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 36:**

All documents and things forming the bases for, refuting, or concerning Impax's contention that the '171, '120 and/or '958 patents are invalid.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 36:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it calls for a legal conclusion in determining documents that are responsive to the request. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 37:**

All documents and things forming the bases for, refuting, or concerning Impax's contention that the '171, '120, and/or '958 patents are unenforceable.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 37:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it calls for a legal conclusion in determining documents that are responsive to the request. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 38:**

All documents and things constituting or concerning any prior art on which Impax intends to rely for its contention that the '171, '120, and/or '958 patents are invalid.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 38:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it calls for a legal conclusion in determining documents that are responsive to the request. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 39:**

All documents and things forming the bases for, refuting, or concerning Impax's contention that the '171, '120, and/or '958 patents are unenforceable due to unclean hands.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 39:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it calls for a legal conclusion in determining documents that are responsive to the request. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 40:**

All documents and things concerning the '171, '120, and/or '958 patents.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 40:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence, and will limit its response to documents and things concerning ANDA 78-057 or the products that are the subject of ANDA 78-057. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 41:**

All documents and things concerning communications or contacts between Impax and third parties concerning the '171, '120, and/or '958 patents.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 41:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence, and will limit its response to documents and things concerning ANDA 78-057 or the products that are the subject of ANDA 78-057. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 42:**

All documents and things concerning any research and development plans, timelines, and/or expenditures for any extended release venlafaxine product.

## **RESPONSE TO REQUEST FOR PRODUCTION NO. 42:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 43:**

All documents and things concerning extended release venlafaxine, including, but not limited to all pharmaceutical, formulary, chemical, and/or medical research concerning extended release venlafaxine.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 43:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

## **REQUEST FOR PRODUCTION NO. 44**:

All documents and things concerning any market research or analysis concerning immediate release venlafaxine or extended release venlafaxine.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 44:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "immediate release" and "extended release" as vague and ambiguous. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057, Effexor, and Effexor XR. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 45:**

All documents and things concerning any extended release venlafaxine product manufactured by or for Impax, including, but not limited to, the design, research, development, composition (including ingredients by name and weight percent), use, testing, manufacture, marketing, and/or sale of such product.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 45:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this

request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# REQUEST FOR PRODUCTION NO. 46:

All documents and things concerning the properties, efficacy, advantages, or utility of an extended release venlafaxine product.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 46:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 47:**

All documents and things concerning the adverse events of an immediate release formulation of venlafaxine.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 47:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "adverse events", "immediate release", and "immediate release formulation of venlafaxine" as vague and

ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request. **REQUEST FOR PRODUCTION NO. 48:** 

All documents and things concerning the alleged bioequivalence between any extended release venlafaxine product manufactured by or on behalf of Impax and EFFEXOR® XR.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 48:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to the term "bioequivalence" as vague and ambiguous and will interpret such as used in connection with FDA submissions. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request. **REOUEST FOR PRODUCTION NO. 49:** 

All documents and things concerning bioequivalence testing done by or for Impax on the products that are the subject of ANDA 78-057.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 49:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "bioequivalence" as vague and ambiguous and will interpret such as used in connection with FDA submissions. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 50:**

All documents and things concerning EFFEXOR® XR.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 50:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege. and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence, and will limit its response to documents and things concerning ANDA 78-057 or the products that are the subject of ANDA 78-057. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

# **REQUEST FOR PRODUCTION NO. 51:**

All documents and things concerning any work, research, tests, experiments, or studies, whether contemplated, planned, complete, incomplete, or prematurely terminated, concerning any extended release venlafaxine product, including any reports or summaries relating thereto.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 51:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REOUEST FOR PRODUCTION NO. 52:**

All documents and things concerning any work, research, tests, experiments, or studies, whether contemplated, planned, complete, incomplete, or prematurely terminated, comparing EFFEXOR® XR to any other venlafaxine product.

# RESPONSE TO REQUEST FOR PRODUCTION NO. 52:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

## REQUEST FOR PRODUCTION NO. 53:

All documents and things concerning any work, research, tests, experiments, or studies, whether contemplated, planned, complete, incomplete, or prematurely terminated, comparing any extended release venlafaxine product manufactured by or for Impax to any other antidepressant.

# **RESPONSE TO REQUEST FOR PRODUCTION NO. 53:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 54:**

All documents and things concerning any analysis, study, investigation, report, or testing by or on behalf of Impax for the development of an extended release venlafaxine product.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 54:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 55:**

All documents and things concerning Impax's plans for advertising Impax Venlafaxine HCl Extended-Release Capsules.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 55:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 56:**

All documents and things concerning Impax's plans for promoting or encouraging the sale and use of Impax Venlafaxine HCl Extended-Release Capsules.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 56:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "plans for promoting or encouraging the sale and use" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

## **REQUEST FOR PRODUCTION NO. 57:**

All documents and things concerning Impax's procedures, protocols and strategies for marketing generic prescription drug products.

## **RESPONSE TO REQUEST FOR PRODUCTION NO. 57:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "procedures", "protocols", "strategies", and "generic" as vague and ambiguous. Impax objects to this request and will not produce documents and things that are responsive to this request because it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence.

## **REQUEST FOR PRODUCTION NO. 58:**

All documents and things concerning any communication with a customer or potential customer, or documents intended for distribution at seminars, trade shows, or other public displays, or intended for distribution to doctors, pharmacists, patients, or healthcare organizations, concerning the Impax Venlafaxine HCl Extended-Release Capsules.

## **RESPONSE TO REQUEST FOR PRODUCTION NO. 58:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 59:**

All documents and things concerning any press release, publicity release, trade release, new product release, or other notice to the trade ever published, printed or caused to be published or printed by or on behalf of Impax, concerning the '171, '120, and '958 patents, this litigation, the products that are the subject of ANDA 78-057, or EFFEXOR® XR.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 59:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "press release", "publicity release", "trade release", and "notice to trade" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 60:**

All documents and things concerning any and all U.S. or foreign patents or patent applications filed by or on behalf of Impax, whether issued, pending or abandoned, that disclose, teach, suggest, describe, or claim in whole or in part an extended release venlafaxine product.

## RESPONSE TO REQUEST FOR PRODUCTION NO. 60:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this

request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### REQUEST FOR PRODUCTION NO. 61:

All documents and things concerning any publications by persons engaged in research on behalf of Impax with respect to venlafaxine or venlafaxine products. RESPONSE TO REQUEST FOR PRODUCTION NO. 61:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence, and will limit its response to documents and things concerning ANDA 78-057 or the products that are the subject of ANDA 78-057. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 62:**

All documents concerning Impax's plans to encourage doctors, pharmacists, patients, and/or healthcare organizations, including, but not limited to HMOs, PPOs, and GPOs, to switch from EFFEXOR® XR to Impax Venlafaxine HCl Extended-Release Capsules.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 62:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "encourage" and "switch" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 63:**

All documents concerning Impax's promotion or planned promotion of Impax Venlafaxine HCl Extended-Release Capsules as a substitute for EFFEXOR® XR. RESPONSE TO REQUEST FOR PRODUCTION NO. 63:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "promotion" and "substitute" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REOUEST FOR PRODUCTION NO. 64:**

All documents and things relating to the marketing, prescription, labeling, or use of Impax Venlafaxine HCl Extended-Release Capsules or EFFEXOR® XR for indications other than or in addition to major depressive disorder.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 64:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 65:**

All documents and things concerning the ways in which Impax intends to notify doctors, pharmacists, hospitals, and health maintenance organizations about the Impax Venlafaxine HCl Extended-Release Capsules or their potential uses.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 65:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 66:**

All documents and things concerning how doctors will prescribe and patients will use Impax Venlafaxine HCl Extended-Release Capsules or EFFEXOR® XR.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 66:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 67:**

All documents and things concerning the market or potential market for antidepressants.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 67:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request and will not produce responsive documents and things because it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. REQUEST FOR PRODUCTION NO. 68:

All documents and things concerning (and from which may be determined)

Impax's projected or anticipated costs, revenue, and profits from its anticipated sales of
any extended-release venlafaxine product.

## RESPONSE TO REQUEST FOR PRODUCTION NO. 68:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege,

and the attorney work-product doctrine. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### REOUEST FOR PRODUCTION NO. 69:

All documents and things concerning Impax's reasons for seeking to produce and/or market an extended release venlafaxine product, including but not limited to market analyses, financial models, and surveys.

### RESPONSE TO REQUEST FOR PRODUCTION NO. 69:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "market", "market analysis", "financial models", and "surveys" as vague and ambiguous. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce nonprivileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 70:**

All documents and things concerning any estimate of sales or demand for an extended release venlafaxine product.

## RESPONSE TO REQUEST FOR PRODUCTION NO. 70:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "demand" as vague and ambiguous. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 71:**

All documents and things concerning the past, present, and projected market share for any extended release venlafaxine product, including but not limited to Impax Venlafaxine HCl Extended-Release Capsules or EFFEXOR® XR.

## **RESPONSE TO REQUEST FOR PRODUCTION NO. 71:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "projected market share" as vague and ambiguous. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057, Effexor, and Effexor XR. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce nonprivileged documents and things that are responsive to this request.

## **REQUEST FOR PRODUCTION NO. 72:**

All documents and things concerning the potential market or potential sales of Impax Venlafaxine HCl Extended-Release Capsules.

## RESPONSE TO REQUEST FOR PRODUCTION NO. 72:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "potential market" and "potential sales" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 73:**

All documents and things concerning public statements, press releases, and/or publications by Impax describing a comparison of generic drugs and branded drugs or the relationship between generic drugs and branded drugs.

### RESPONSE TO REQUEST FOR PRODUCTION NO. 73:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "public statements", "press releases", "publications", "generic", "branded", and "relationship" as vague and ambiguous. Impax objects to this request and will not produce responsive documents and things because it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence.

#### **REQUEST FOR PRODUCTION NO. 74:**

All documents and things identifying and concerning each person's (including but not limited to employees, agents, representatives, consultants, contractors, and collaborators) participation in the research, development, design, manufacture, use, testing, or marketing of any extended release venlafaxine product, including but not limited to the products that are the subject of ANDA 78-057, as well as all documents identifying and concerning where and when such activity took place.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 74:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "marketing" as vague and ambiguous. Impax objects to Wyeth's definition of the term "venlafaxine product" and will limit documents and things produced in response to this request to the products that are the subject of ANDA 78-057. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

## **REQUEST FOR PRODUCTION NO. 75:**

All documents and things identifying and concerning all of Impax's consultations with consultants, experts, and clinicians regarding the research, development, manufacture, design, testing, and analysis of the products that are the subject of ANDA 78-057.

## RESPONSE TO REQUEST FOR PRODUCTION NO. 75:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the terms "consultations" and "analysis" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

## **REQUEST FOR PRODUCTION NO. 76:**

All documents and things concerning any document retention policy, program, or practice at Impax.

## RESPONSE TO REQUEST FOR PRODUCTION NO. 76:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request because it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request concerning the products that are the subject of ANDA 78-057.

## REQUEST FOR PRODUCTION NO. 77:

All documents and things concerning any document destruction policy, program, or practice at Impax.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 77:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request concerning the products that are the subject of ANDA 78-057.

#### **REQUEST FOR PRODUCTION NO. 78:**

All documents concerning Impax's organizational structure and departmental management for research, development, manufacture, testing, production, assembly, marketing, distribution, regulatory approval, and sales of pharmaceutical products from 1996 to the present.

#### RESPONSE TO REQUEST FOR PRODUCTION NO. 78:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence, and will limit its response to documents and things concerning ANDA 78-057 or the products that are the subject of ANDA 78-057. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### REQUEST FOR PRODUCTION NO. 79:

All documents concerning the organizational relationship between Impax and all corporations related to Impax from 1996 to the present.

### **RESPONSE TO REQUEST FOR PRODUCTION NO. 79:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence, and will limit its response to documents and things concerning ANDA 78-057 or the products that are the subject of ANDA 78-057. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

## **REQUEST FOR PRODUCTION NO. 80:**

Impax's annual reports to shareholders, annual and quarterly profit and loss statements, form 10-K reports to the Securities and Exchange Commission, and any prospectus prepared or filed since January 1, 1997.

## RESPONSE TO REQUEST FOR PRODUCTION NO. 80:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Impax objects to this request and will not produce documents and things responsive to it because the documents sought are publicly available and can be obtained directly from the third parties.

#### REQUEST FOR PRODUCTION NO. 81:

All documents and things concerning IMS data, Medco data, Scott-Levin audit data, or other similar data from third party providers regarding sales, prescriptions, or costs concerning EFFEXOR® XR.

## **RESPONSE TO REQUEST FOR PRODUCTION NO. 81:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Impax objects to this request and will not produce documents and things responsive to it because the publicly available documents and things sought can be obtained directly from the third parties.

## REQUEST FOR PRODUCTION NO. 82:

All documents identified in response to or relied upon or referred to in responding to Plaintiffs First Set of Interrogatories to Defendant Impax.

### **RESPONSE TO REQUEST FOR PRODUCTION NO. 82:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 83:**

All documents and things identified in Impax's Rule 26 Initial Disclosures served on June 23, 2006.

## RESPONSE TO REQUEST FOR PRODUCTION NO. 83:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the

extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REQUEST FOR PRODUCTION NO. 84**:

All documents generated, considered or received by Charles Hsiao in connection with the development of Impax's Venlafaxine HCl Extended-Release Capsules.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 84:**

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "considered" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

#### **REOUEST FOR PRODUCTION NO. 85:**

All documents generated, considered or received by Mark C. Shaw in connection with the preparation and/or filing of ANDA 78-057.

### RESPONSE TO REQUEST FOR PRODUCTION NO. 85:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to the term "considered" as vague and ambiguous. Impax objects to this request to the extent it is overly broad, unduly

burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

## **REQUEST FOR PRODUCTION NO. 86:**

All documents between Impax and any third party concerning EFFEXOR® XR. RESPONSE TO REQUEST FOR PRODUCTION NO. 86:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence, and will limit documents and things produced in response to this request to communications concerning ANDA 78-057 or the products that are the subject of ANDA 78-057. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

## **REQUEST FOR PRODUCTION NO. 87:**

All documents between Impax and any third party concerning the '171, '120, and/or '958 patents.

## RESPONSE TO REQUEST FOR PRODUCTION NO. 87:

Impax objects to this request on the grounds set forth in the General Objections, incorporated by reference as if fully set forth herein. Impax objects to this request to the extent it calls for documents and things that are protected by the attorney-client privilege, and the attorney work-product doctrine. Impax objects to this request to the extent it is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence, and will limit documents and things produced in response to this request to communications concerning ANDA 78-057 or the products

that are the subject of ANDA 78-057. Subject to and without waiving the foregoing objections, Impax will produce non-privileged documents and things that are responsive to this request.

Dated: July 26, 2006

PATRICIA THAYER (pro hac vice)

JOHN M. BENASSI (pro hac vice) JESSICA R. WOLFF (pro hac vice) SAMUEL F. ERNST (pro hac vice)

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Attorneys for Defendant IMPAX LABORATORIES, INC.

## CERTIFICATE OF SERVICE

I hereby certify that on the 26<sup>th</sup> day of July, 2006, the foregoing document,
DEFENDANT IMPAX LABORATORIES, INC.'S RESPONSES TO PLAINTIFF'S
FIRST REQUEST FOR THE PRODUCTION OF DOCUMENTS AND THINGS
(NOS. 1-87), was served on counsel via U.S. Mail:

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Dated: July 26, 2006

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# EXHIBIT 2



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LINDA A. WADLER 202.408.4037 linda.wadler@finnegan.com

August 4, 2006

Jessica R. Wolff, Esq. Heller Ehrman LLP 4350 La Jolla Village Drive, 7<sup>th</sup> Floor San Diego, CA 92101 Via Facsimile

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Jessica:

I am writing to set forth Wyeth's concerns with respect to Defendant's objections and responses to Wyeth's first set of document requests.

First, Impax's General Objection No. 3 objects to Wyeth's definition of the term "venlafaxine product" and improperly seeks to limits its production to products that are the subject of ANDA No. 78-057, Effexor® and Effexor® XR. Impax's development of the products that are the subject of ANDA No. 78-057, including its possible consideration of alternative extended release venlafaxine formulations prior to the filing of that ANDA is relevant to issues of infringement in this litigation. Notably, Impax has sought documents relating to all venlafaxine formulations from Wyeth. See, for example, Impax Document Request Nos. 7-21, 41, 46 and 74. In addition, documents concerning any consideration by Impax of development of an immediate release venlafaxine product as well as any documents concerning the adverse events of nausea and vomiting associated with immediate release venlafaxine products are also relevant and should be produced. Please confirm that Impax will withdraw this objection, and let us know which, if any, documents Impax is withholding based on the above objections

Many of Impax's specific objections are unacceptable for the same reason. Impax's specific objections to Wyeth Document Request Nos. 8-9, 18, 23, 25-28, 42-45, 51-54, 68-71, and 74 limiting production to documents concerning the accused products and ANDA No. 78-057 exclude potentially relevant documents concerning Impax's consideration of alternative extended release venlafaxine formulations prior to the filing of its ANDA 78-057 as well as Impax documents concerning Effexor® XR, including but not limited to research, timelines and/or expenditures regarding Effexor® XR. Impax's specific objections to Wyeth Document Request Nos. 46, 50, 61 and 86-87 improperly exclude documents concerning the commercial embodiment of the patents in suit,

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Effexor® XR, including documents concerning the properties, efficacy, advantages, or utility of Effexor® XR which are relevant to the validity of the patents-in-suit and public statements about that product. Please confirm that Impax will withdraw the objection, and let us know which, if any, documents Impax is withholding based on the above objections.

Similarly, Impax's specific objection to Wyeth Document Request Nos. 11 and 44 limiting production to the accused products, Effexor® and Effexor® XR is also without basis. Documents concerning the adverse events of nausea and vomiting associated with any immediate release venlafaxine product or any consideration by Impax of development of a generic immediate release venlafaxine product are relevant. Please confirm that Impax will withdraw the objection, and let us know which, if any, documents Impax is withholding based on the above objections.

In the same vein, Impax's specific objection to Wyeth Document Request No. 30 limiting production of communications between Impax and third parties concerning venlafaxine to the accused products excludes potentially relevant documents concerning alternative extended release venlafaxine formulations prior to the filing of ANDA No. 78-057. Documents concerning the adverse events of nausea and vomiting associated with any immediate release venlafaxine products as well as any consideration by Impax of development of a generic immediate release venlafaxine product are also relevant. Please confirm that Impax will withdraw the objection, and let us know which, if any, documents Impax is withholding based on the above objections.

We do not understand Impax's specific objections to Wyeth Document Request Nos. 40-41. Those requests seek documents concerning the patents in suit, yet Impax has objected to those requests limiting "its response to documents and things concerning ANDA 78-57 or the products that are the subject of ANDA 78-57." Please confirm that Impax will withdraw the objection, and let us know which, if any, documents Impax is withholding based on the above objections.

Finally, Impax's specific objections to Wyeth Document Request Nos. 78-79 limiting "its response to documents and things concerning ANDA 78-57 or the products that are the subject of ANDA 78-57" potentially excludes relevant documents concerning departments or affiliates at Impax that may have developed an immediate release venlafaxine product. Please confirm that Impax will withdraw this objection and let us know which, if any, documents Impax is withholding based on the above objections.

Impax's General Objection No. 8 objects to requests for production on the basis of "privacy rights," Including those of Impax's employees. We do not understand this objection. We assume that Impax will appropriately redact requested, relevant documents to remove patient privacy information, for example patient identifying

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information or social security numbers etc., and produce the redacted document, rather than withholding the entire document. If this assumption is not accurate, please notify us immediately. Please identify any other "privacy" rights to which you refer, and please identify to us what it is that Impax plans to withhold and the basis for the withholding.

Impax's General Objection Nos. 9-10 object to "each and every request" to the extent it is "overly broad and unduly burdensome or oppressive" or "vague and ambiguous." Because those objections lack any specificity, we are unable to determine whether Impax is withholding requested, relevant documents on the basis of Impax's unilateral determination of ambiguity, breath or burden. Thus, we request that you withdraw these general objections, or let us know whether Impax is withholding any documents or information based on these objections, and if so, identify the documents and information it is withholding.

Similarly with respect to General Objection No. 12, Impax objects to "each and every request" to the extent it "calls for documents or things that are neither relevant to the subject matter of this action nor reasonably calculated to lead to the discovery of admissible evidence." Because that objection lacks any specificity, we are unable to determine whether Impax is withholding requested, relevant information on the basis of Impax's unilateral determination of relevance.

Impax further indicates in General Objection No. 12 that Wyeth withdrawal of its willfulness allegation will impact its relevance determinations. This would be inappropriate to the extent it is intended to prevent discovery of documents or information regarding, for example, Impax's awareness and consideration of the patents-in-suit, its decision to develop an extended release venlafaxine product, its decision to file an ANDA covering such a product or its bases for any of its paragraph IV certifications. Separate and aside from the issue of exceptional case which still remains in the litigation, such information is clearly relevant to issues of claim construction, infringement, both literal and under the doctrine of equivalents, and validity. Impax has no basis on which to withhold documents or information regarding its knowledge of the patents in suit or its decision to develop an extended release venlafaxine product or file an ANDA covering such a product with a Paragraph IV certification. Thus, we request that you withdraw General Objection No. 12 or let us know whether Impax is withholding any documents or information based on these objections, and if so, identify the documents and information it is withholding.

Similarly, Impax's specific objections to virtually every single one of Wyeth Document Request Nos. 1-87 as "overly broad, unduly burdensome, oppressive and not reasonably calculated to lead to the discovery of admissible evidence" without specific identification of the documents, if any, that Impax is withholding pursuant to those objections, is unacceptable. Please let us know whether Impax is withholding any

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documents or information based on these objections, and if so, identify the documents and information it is withholding.

We also note that Impax has made many "vague and ambiguous" objections to requests containing commonly used terms. We do not understand those objections. Please let us know whether Impax is withholding any documents on the basis of the below-identified "vague and ambiguous" objections to the following requests, and if so please identify the documents being withheld on that basis. If any documents are being withheld, please also explain Impax's basis for contending that the requests are "vague" and ambiguous":

- Wyeth Document Request No. 5 on the basis of its objection that the term "that resulted in" is vague and ambiguous;
- Wyeth Document Request Nos. 6-9 on the basis of its objection that the term "in vitro dissolution testing" is vague and ambiguous;
- Wyeth Document Request No. 16 on the basis of its objection that the terms "analysis," "study," "investigation," "testing," and "report" are vague and ambiguous;
- Wyeth Document Request No. 17 on the basis of its objection that the terms "materials," "process used to manufacture," and "market" are vague and ambiguous;
- Wyeth Document Request Nos. 26-27 on the basis of its objection that the terms "market," and "decision to market" are vague and ambiguous;
- Wyeth Document Request Nos. 32-33 on the basis of its objection that the terms "studies," "reports," "opinions," "conferences," "interviews," and "analyses" are vague and ambiguous;
- Wyeth Document Request No. 47 on the basis of its objection that the terms "adverse events," "immediate release," and "immediate release formulation of venlafaxine," are vague and ambiguous;
- Wyeth Document Request No. 56 on the basis of its objection that the term "plans for promoting or encouraging the sale and use" is vague and ambiguous;
- Wyeth Document Request No. 57 on the basis of its objection that the terms "procedures," "protocols," "strategies," and "generic" are vague and ambiguous;

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- Wyeth Document Request No. 59 on the basis of its objection that the terms "press release," "publicity release," "trade release," and "notice to trade" are vague and ambiguous;
- Wyeth Document Request No. 62 on the basis of its objection that the terms "encourage" and "switch" are vague and ambiguous;
- Wyeth Document Request No. 63 on the basis of its objection that the terms "promotion" and "substitute" are vague and ambiguous;
- Wyeth Document Request No. 69 on the basis of its objection that the terms "market," "market analysis," "financial models," and "surveys" are vague and ambiguous;
- Wyeth Document Request No. 70 on the basis of its objection that the term "demand" is vague and ambiguous;
- Wyeth Document Request No. 71 on the basis of its objection that the term "projected market share" is vague and ambiguous;
- Wyeth Document Request No. 72 on the basis of its objection that the terms "potential market" and "potential sales" are vague and ambiguous;
- Wyeth Document Request No. 73 on the basis of its objection that the terms "public statements," "press releases," "publications," "generic," "branded," and "relationship" are vague and ambiguous;
- Wyeth Document Request No. 74 on the basis of its objection that the term "marketing" is vague and ambiguous;
- Wyeth Document Request No. 75 on the basis of its objection that the terms "consultations" and "analysis" are vague and ambiguous; and
- Wyeth Document Request Nos. 84-85 on the basis of its objection that the term "considered" is vague and ambiguous.

Impax objects to producing documents in response to Wyeth Document Request No. 80 "because the documents sought are publicly available and can be directly obtained from the third parties." This objection is improper to the extent it seeks to exclude from production responsive public documents within Impax's possession, custody, and control. Is Impax excluding from its production responsive documents located in its files on the basis that they are publicly available?

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER !!!

We look forward to receiving a response from you by August 10<sup>th</sup>. We hope that we are able to satisfactorily resolve the concerns raised herein in a timely fashion, so that the assistance of the Court is not necessary.

Linda A. Wadler

LAW/RAP/amn

Mary B. Matterer, Esq. (via Facsimile) CC: Richard K. Herrmann, Esq. (via Facsimile)

# EXHIBIT 3

## HellerEhrmanup

August 21, 2006

Via E-mail

Samuel F. Ernst Sam.Ernst@hellerehrman.com Direct +1.415.772.6964 Direct Fax +1.415.772.1759 Main +1.415.772.6000 Fax +1.415.772.6268

40443.0005

Linda A. Wadler, Esq. Finnegan Henderson Farabow Garrett & Dunner LLP 901 New York Ave., N.W. Washington, DC 20001-4413

Re: Wyeth v. Impax Laboratories, Inc., No. 06-222 (D. Del.)

Dear Linda:

This letter is in response to your letters of August 3 and 4 to Ms. Wolff regarding Impax's responses to Wyeth's first set of document requests and first set of interrogatories. This letter also addresses certain deficiencies in Wyeth's responses to Impax's discovery requests.

## Objections regarding the timing of discovery of party contentions

You have raised concerns regarding Impax's responses to Wyeth's interrogatories nos. 1 through 3 seeking Impax's contentions regarding noninfringement and invalidity.

Impax believes it has adequately responded to interrogatory no. 1 at this early stage of the litigation by, *inter alia*, explaining that Impax's products do not infringe because they do not contain microcrystalline cellulose, a limitation present in each claim of the patents-in-suit either explicitly or as properly construed.

Impax believes it has adequately responded to interrogatories nos. 2 and 3 at this early stage of the litigation by explaining that the claims of the patents-in-suit are invalid as anticipated pursuant to 35 U.S.C. § 102 or rendered obvious pursuant to 35 U.S.C. § 103 and by listing the prior art references Impax is currently aware of that render the claims invalid under these provisions. Further, Impax has explained that in the unlikely event the Court construes "extended release formulation" as not comprising microcrystalline cellulose, the patents-in-suit are invalid pursuant to 35 U.S.C. § 112 for lack of enablement and for lack of a written description.

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Anchorage Beijing Hong Kong Los Angeles Madison, WI New York San Diego San Francisco Seattle Silicon Valley Singapore Washington, D.C.

## HellerEhrmanur

Linda A. Wadler, Esq. August 21, 2006 Page 2

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We note that Impax's responses to these interrogatories are much more detailed and responsive than Wyeth's responses to Impax's interrogatories nos. 9 and 17 seeking Wyeth's contentions regarding infringement and invalidity. Wyeth has failed to identify a single ingredient of Impax's accused formulations that meet a limitation of the asserted claims in response to interrogatory no. 9. In response to interrogatory no. 17, Wyeth has failed to identify a single secondary consideration that it contends supports a finding of non-obviousness, much less the factual and legal basis for any such contention.

Both parties have raised objections to these contention interrogatories as premature because, *inter alia*, expert discovery has not yet occurred and because fact discovery is ongoing. See Wyeth's Resps. to Def. Impax's First Set of Interrogs. at 27 ("Wyeth also objects to Interrogatory No. 9 as premature because, under the Court's Scheduling Order, initial expert reports are not due until September 28, 2007."), 37 ("Wyeth objects to this interrogatory as premature because fact discovery is just beginning and, under the Court' Pretrial Scheduling Order, Wyeth's rebuttal expert reports are not due until October 31, 2007."). Consideration of infringement and invalidity further requires disputed claim terms to be construed and, as Wyeth has pointed out, "the Court has set April 13, 2007 as the date for parties to exchange proposed claim constructions." *Id.* at 23.

Accordingly, Impax suggests a compromise regarding these contention interrogatories that will account for both parties' need to receive discovery of contentions prior to trial and both parties' objections regarding timing. Specifically, Impax suggests that the parties agree to exchange infringement and invalidity contentions on a schedule and sequence modeled after that provided for by the Patent Local Rules of the Northern District of California. (available at http://www.cand.uscourts.gov/). Specifically, Impax proposes as follows:

- Wyeth will serve on Impax a "Disclosure of Asserted Claims and Preliminary Infringement Contentions," as defined in N.D. Cal. Patent L.R. 3-1, including the document production accompanying this disclosure pursuant to N.D. Cal. Patent L.R. 3-2, by August 28, 2006.<sup>2</sup>
- Impax will serve on Wyeth its "Invalidity Contentions," as defined in N.D. Cal. Patent L.R. 3-3, including the document production accompanying this disclosure pursuant to Patent L.R. 3-4, by October 10, 2006.

<sup>&</sup>lt;sup>1</sup> Other courts, such as the Eastern District of Texas, have adopted these rules and many courts have adopted them on an ad hoc basis.

<sup>&</sup>lt;sup>2</sup> We note that Wyeth is in a position to make this disclosure now, as Impax has already produced to Wyeth its ANDA, which details the ingredients of the accused products.

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Linda A. Wadler, Esq. August 21, 2006 Page 3

These dates are calculated to achieve completion of the exchange of party contentions by the October 31, 2006 deadline for completion of contention interrogatories. As provided for in N.D. Cal. Patent L.R. 3-3, Impax's invalidity contentions would be due approximately 45 days after Impax's infringement contentions. We are willing to negotiate the precise details of such an exchange, however, and would suggest that the parties meet and confer on this proposed compromise.

## Objections regarding the scope of discovery on the claimed and accused products

Impax has objected to Wyeth's demand for documents and interrogatories related to all proposed, experimental, and commercial products containing the active ingredient venlafaxine hydrochloride. Documents regarding products that are not the subject of ANDA 78-057, are not accused in this litigation, and are not related to EFFEXOR® or EFFEXOR® XR are not relevant to the claims at issue in this litigation.

In response to Impax's document request no. 7, Wyeth itself has objected to providing documents regarding EFFEXOR® other than those "reflecting (1) comparisons between immediate release Effexor® and Effexor® XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor®." This is far narrower than the categories of documents regarding EFFEXOR® Impax has agreed to produce. We fail to understand why Wyeth expects Impax to conform to a set of rules that it does not intend to follow itself.

## Objections regarding the definitions of the parties

In a similar vein, Wyeth objects to Impax defining itself to exclude persons and entities other than "the corporate entity named as defendant in this action, its officers and its agents," even though Wyeth itself has decided to exclude from its discovery obligations a search for documents in its foreign locations and facilities or in the possession of its former officers, directors, or agents. Impax has a specific need for Wyeth's foreign documents, given that Wyeth performed experiments in support of its NDA overseas and prosecuted foreign equivalents to the patents-in-suit overseas. Wyeth, on the other hand, has not stated which entities or persons Impax has excluded from the definition of "Impax" from which Wyeth requires documents.

The appropriate compromise to this dispute is for the parties simply to agree to fulfill their obligation to search for all responsive documents in their "possession, custody, or control." FED. R. CIV. P. 34(a). "In the context of Fed. R.Civ. P. 34(a), so long as the party has the legal right or ability to obtain the documents from another source upon demand, that party is deemed to have control." *Mercy Catholic Med. Ctr. v. Thompson*, 380 F.3d 142, 160 (3d Cir. 2004). If Wyeth will confirm that it will follow its obligation to produce all responsive documents it "has the legal right or ability to obtain," including those at its foreign

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Linda A. Wadler, Esq. August 21, 2006 Page 4

facilities, Impax will withdraw the portion of its motion to compel seeking Wyeth's compliance with Rule 34(a).

## Objections regarding production of documents and responses to interrogatories regarding Wyeth's withdrawn claim of willful infringement.

Wyeth contends that it is entitled to discovery regarding Impax's "awareness and consideration of the patents-in-suit, its decision to develop an extended release venlafaxine product, its decision to file an ANDA covering such a product or its bases for any of its Paragraph IV certifications," even though it has withdrawn its claim of willful infringement. Wyeth contends that this discovery is relevant to its claim that this is an "exceptional case." However, a party may only recover attorneys fees under Section 285 if it is the "prevailing party." 35 U.S.C. § 285. Accordingly, Section 285 discovery properly occurs only after there has been an adjudication on the merits. Scutellaro v. Walt Disney Co., 1993 WL 393003 (D. Del. Sept. 24, 1993).

Wyeth next contends that such discovery is relevant to the issues of "claim construction, infringement, both literal and under the doctrine of equivalents, and validity." We fail to see how discovery of Impax's awareness of the patents-in-suit or its decision to file an ANDA is relevant to the proper construction of Wyeth's patents, their validity, or to the question as to whether those patents are infringed. We will, however, review any authority Wyeth cites to support this proposition.

## Objections regarding document requests that would invade the privacy rights of Impax, its employees, or nonparties to the litigation.

We agree that to the extent Impax is required to produce documents that would invade the privacy rights of Impax, its employees, or nonparties to the litigation, Impax will produce such documents in redacted form.

## Objections to interrogatories seeking the ingredients of the accused products and their functions

Wyeth must have been aware of the ingredients of the accused products and their functions at the time it filed its complaint in order to comply with its obligations under Federal Rule of Civil Procedure 11. Cambridge Prods., Ltd. v. Penn Nutrients, Inc., 962 F.2d 1048, 1050 (Fed. Cir. 1992) (patentee satisfied its Rule 11 obligations by performing an independent chemical analysis of the accused products prior to filing suit). Moreover, Impax informed Wyeth of the ingredients of the accused products and their functions in its February 21, 2006 notification to Wyeth of Impax's ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95. To the extent Wyeth feels this disclosure is for some reason incomplete, Impax has properly responded that it will rely on the option to produce business

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Linda A. Wadler, Esq. August 21, 2006 Page 5

records pursuant to Rule 33(d) to respond to this interrogatory. Indeed, this information is readily available in Impax's ANDA, which Impax has already produced to Wyeth.

## Impax's response to interrogatory seeking the identify of each individual involved in the development of the accused products

Wyeth is incorrect that Impax failed to respond Wyeth's Interrogatory No. 12, seeking the identity of each individual involved in the development of the accused products. Rather, Impax has answered that it will rely on the option to produce business records containing this information, pursuant to Rule 33(d).

We note that Wyeth has invoked Rule 33(d) as well in response to Impax's interrogatories nos. 3, 11, 12, 13, 17, 18, and 19. We propose that the parties meet and confer to determine a date on which the parties will provide to the other side a specification of the documents relied upon in support of their Rule 33(d) invocations and where in the produced documents the requested information may be found.

In any event, Impax's response to Wyeth's interrogatory no. 12 is far more responsive than Wyeth's response to Impax's interrogatory no. 1. Impax asked Wyeth to identify all persons with knowledge of the facts alleged in the complaint. Wyeth limited its response to persons having knowledge of whether the accused products infringe the patents-in-suit and gave the unhelpful answer that Wyeth's litigation counsel and Impax's employees, agents, or attorneys are likely to have this knowledge. Impax is entitled to know which of Wyeth's employees, agents, or attorneys have knowledge of each of the facts alleged in the complaint. Please supplement Wyeth's response to Impax's interrogatory no. 1.

#### Wyeth's refusal to produce documents regarding its pre-filing investigation

Impax's interrogatory no. 8 asked Wyeth to identify any investigation or analysis it conducted to determine whether the accused products infringe the patents-in-suit and to identify each person involved in any such investigation. Wyeth has failed to identify a specific investigation or analysis it performed prior to filing this lawsuit. Instead, Wyeth has merely stated that litigation counsel were involved in an analysis of whether the accused products infringe.

This response is insufficient. Impax is entitled to know the specific experiments, analysis, or investigations Wyeth conducted in order to comply with its Rule 11 pre-filing obligations and the persons who performed those analyses because this information is relevant to Impax's defense of unclean hands. We request that Wyeth supplement its interrogatory response and provide this information. If Wyeth refuses to supplement, we will take this refusal as a concession that no person or scientist at Wyeth performed a pre-filing

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Linda A. Wadler, Esq. August 21, 2006 Page 6

chemical analysis or any other investigation of the accused products before Wyeth proceeded with this lawsuit.

#### Wyeth's refusal to produce its complete NDA

In your letter of August 11 you state that Wyeth will not produce the remainder of Wyeth's NDA for Effexor® XR, but will consider producing additional portions of the NDA if "Impax can articulate a particular need for selected information identified in the table of contents associated with an NDA volume number." Impax's position is that Wyeth is obligated to produce its entire NDA. However, we will complete our review of the materials you have provided us to determine whether we require the remainder of the NDA and we reserve our right to discover the remaining portions of the NDA.

In any event, we do require Wyeth's past and ongoing correspondence with the FDA, including changes in labeling and adverse event reports. Please tell us when Wyeth will be producing these documents.

#### Draft protective order

We provided a draft protective order to you on July 12. To date you have not told us whether Wyeth agrees to the terms of that order. We enclose herein a new draft protective order with an additional provision we have added in redline. Please inform us as soon as possible whether Wyeth agrees to the terms of this order.

Samuel F. Ernst

Enclosure

# EXHIBIT 4



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LINDA A. WADLER
202.408.4037
linda.wadler@finnegan.com

September 7, 2006

Samuel F. Ernst, Esq. Heller Ehrman LLP 333 Bush Street San Francisco, CA 94104-2828 Via Facsimile

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Samuel:

I write further with respect to your letter of August 21, 2006 and as a follow up to my letter of August 29<sup>th</sup> to which we have not received a response.

Impax contends that "[d]ocuments regarding products that are not the subject of ANDA 78-057, are not accused in this litigation, and are not related to EFFEXOR® or EFFEXOR XR® are not relevant to the claims at issue in this litigation." Impax further contends that discovery concerning Impax's awareness and consideration of the patents-in-suit, its decision to develop an extended release venlafaxine product, its decision to file an ANDA covering such a product or its bases for its Paragraph IV certifications is either not relevant or not ripe for discovery.

Impax's development of the products that are the subject of ANDA No. 78-057, including its possible consideration of alternative extended release venlafaxine or immediate release venlafaxine formulations prior to the filing of that ANDA is relevant to issues of infringement in this litigation as well as Impax's invalidity defenses at least with respect to issues of obviousness and enablement. For example, any testing on an immediate release formulation of venlafaxine, whether on Effexor® or on any immediate release venlafaxine product developed by Impax, clearly is relevant to Impax's knowledge of the advantages of the patented invention over immediate release venlafaxine. While Impax states that such information is not relevant to the claims at issue in this litigation, several of the asserted method claims reference a reduction in side effects with extended release venlafaxine relative to immediate release venlafaxine.

Impax's awareness and consideration of the patents-in-suit, for example, is relevant to issues such as obviousness, doctrine of equivalents infringement, and enablement. Did Impax use the teachings in the patents-in-suit to develop its own products? Did Impax copy Wyeth's invention? Did Impax choose interchangeable

Case 1:06-cv-00222-JJF Samuel F. Ernst, Esq. September 7, 2006 Page 2

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ingredients to make its product? The answers to these questions are directly relevant to Impax's defenses of noninfringement and invalidity. See, e.g., Hilton Davis Chem. Co. v. Warner-Jenkinson Co., Inc., 62 F.3d 1512, 1519 (Fed. Cir. 1995) (en banc) ("copying suggests that the differences between the claimed and accused products or processes -measured objectively-are insubstantial"), aff'd in part, rev'd in part, 520 U.S. 17 (1997); Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272 (Fed. Cir. 2000) (development evidence of copying supports a claim of infringement under the doctrine of equivalents and nonobviousness). Similarly, Impax's consideration of the commercial success of the commercial embodiment of the patents-in-suit, Effexor® XR, in its decision to develop a generic copy of that product is relevant to issues of obviousness.

We further note that, to date, Impax has only produced its ANDA, and has given no indication that it intends to produce any other documents. Does Impax contend that documents concerning research and development of the products that are the subject of its ANDA--such as laboratory notebooks, research reports and memoranda, e-mail correspondence among researchers, technicians, and managers, and project reports and meeting minutes, for example--are also not relevant to the issues in the case? Likewise, does Impax contend that its own market research and sales projections are also not relevant? When does Impax expect to produce such documents?

As a result of Impax's silence on these issues, we again ask that you represent whether Impax will produce (and specifically when Impax will produce) to Wyeth documents from its files concerning:

- (1) the development of the product that is the subject of ANDA 78-057, including all laboratory notebooks and all in vitro dissolution testing in connection with all of Impax's programs to develop an extended release dosage form of venlafaxine,
- (2) Impax's consideration of alternate extended release venlafaxine formulations prior to the filing of ANDA 78-057,
- (3) Impax's consideration of development of a generic immediate release venlafaxine formulation prior to the filing of ANDA 78-057,
- (4) comparisons between immediate release venlafaxine and extended release venlafaxine,
- (5) nausea and/or vomiting in humans associated with immediate release venlafaxine,
- (6) all documents concerning Effexor® XR,
- (7) Impax's awareness and consideration of the patents-in-suit,

Samuel F. Ernst, Esq. September 7, 2006 Page 3

FINNEGAN HENDERSON FARABOW GARRETT & DUNNERLLP

- (8) Impax's decision to develop an extended release venlafaxine product,
- (9) Impax's decision to file an ANDA covering such a product, and
- (10) Impax's bases for its Paragraph IV certification.

If we do not receive that representation by the end of this week, we will assume that Impax's position is that it intends to withhold such discovery and we will have no choice but to seek the Court's assistance with a motion to compel.

Finally, we note that we are still waiting for a response to pages 3-5 of my August 4<sup>th</sup> letter which identifies, in detail, concerns about both Impax General Objections 9-10 and 12 as well as Impax's myriad, specific objections to identified document requests. In addition, Impax still has not responded to our letter of August 3<sup>rd</sup> specifically requesting that Impax inform Wyeth whether there are any documents or information that Impax is withholding based on its numerous objections of breadth, ambiguity, burden, or relevance, i.e. General Objections Nos. 9-10 and 12.

If we do not receive a response by the end of this week, we will assume we have reached an impasse on these issues as well.

Sincerely,

Linda A. Wadler

LAW/AMM/hkr

cc: Mary B. Matterer, Esq.
Richard K. Herrmann, Esq.

# EXHIBIT 5



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LINDA A. WADLER 202.408.4037 linda.wadler@finnegan.com

September 11, 2006

Jessica R. Wolff, Esq. Heller Ehrman LLP 4350 La Jolla Village Drive, 7<sup>th</sup> Floor San Diego, CA 92101 Via Facsimile

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Jessica:

I am writing to memorialize the substance of our telephonic meet and confer on Friday afternoon, September 8, 2006.

First, you requested that we consider using a discovery master to resolve outstanding discovery disputes between the parties. We will get back to you regarding this proposal.

Next, you requested that we consider an agreement between the parties that <u>all</u> oral and written communications between outside experts and attorneys, including but not limited to draft expert reports, would not be discoverable. The bases of the expert's opinion would remain discoverable, excluding communications with attorneys. Again, we will get back to you regarding this proposal.

You indicated that your firm would get back to us early this week with any comments that you have regarding our proposed revisions to the draft protective order. In response to my request, you are checking to confirm whether the information you sent us regarding your proposed outside consultants, Dr. Spilker and Dr. Kibbey, is complete with respect to (i) a list of companies for whom such person has consulted in any capacity within the last year, (ii) a list of any other cases in which such person has testified as an expert at trial or by deposition within the preceding four (4) years; and (iii) a list of all publications authored by such person within the preceding ten (10) years, as required by the current draft protective order. You said that you will write to us this week to either confirm that the information provided is complete or to supplement. I indicated that if the information is not complete, Wyeth might require additional time in which to object to disclosure of Wyeth confidential information.

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You requested that Wyeth consider a stipulation "to reduce document production" wherein Impax would stipulate to Effexor® XR's commercial success in terms of sales, but not the nexus between those sales and the patented invention. We will get back to you on this proposal.

I pointed out that Impax had produced only one box containing ANDA materials on August 4<sup>th</sup> and that over a month had passed without any additional production. You indicated that Impax's intent was to provide us with a rolling production and not withhold documents until the last day, but were unable to tell us when the next production would be or whether we would receive any additional documents next week. We asked that you follow up to provide us some dates by which we can expect to receive production from Impax.

With respect to Impax's response to Wyeth Interrogatory No. 12, you indicated that Impax will not provide Wyeth with a listing of individuals involved in the development of the accused products or a description of their contribution, but instead will continue to rely on Rule 33(d) as a response. You offered a "compromise" to agree to a time for exchange of and identification of specific documents that would identify such individuals, notwithstanding that the burden of identifying such specific documents would be much greater on Wyeth. I declined that offer in view of Wyeth's response to Impax's Interrogatory No. 3 which identified by name several individuals involved in the research and development of Effexor® XR along with a general description of the nature of their involvement. If Impax does not identify by name and contribution the primary individuals involved in the research and development of the accused infringing products by the close of business tomorrow, we may approach the Court for assistance with this matter.

We next discussed Impax's general objections. You represented that Impax would produce non-privileged documents concerning the development of the product that is the subject of ANDA 78-057, including all laboratory notebooks and all *in vitro* dissolution testing in connection with that product. However, you indicated Impax would not produce development documents concerning any formulations other the product that is the subject of that ANDA.

Specifically, you represented that Impax would <u>not</u> produce non-privileged documents concerning:

(1) Impax's consideration of alternate extended release venlafaxine formulations prior to the filing of ANDA 78-057, even if such consideration led up to the decision to pursue the formulations that are the subject of ANDA 78-057,

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- (2) Impax's consideration of development of a generic immediate release venlafaxine formulation prior to the filing of ANDA 78-057,
- (3) Impax's awareness and consideration of the patents-in-suit<sup>1</sup>,
- (4) comparisons between immediate release venlafaxine and extended release venlafaxine unless they are a comparison between immediate release venlafaxine and the product that is the subject of ANDA 78-057;
- (5) nausea and/or vomiting in humans associated with immediate release venlafaxine, unless it relates to a submission in ANDA 78-057, and
- (6) all documents concerning Effexor® XR, unless it relates to the product that is the subject of ANDA 78-057.

In addition, you indicated that with respect to Impax's decision to develop an extended release venlafaxine product and Impax's decision to file an ANDA covering such a product, Impax's production would be limited to information concerning only the accused infringing product. As an example, you stated that if Impax had considered alternative formulations before choosing the formulation of the accused infringing product, information on the alternative formulations would be redacted from the document(s). You further indicated that Impax would not produce any documents concerning any proposals brought to it by a third party for a venlafaxine product.

As we indicated at the meet and confer and in our correspondence, we believe that the matters you seek to exclude are plainly relevant and we may file a motion to compel their production. We asked whether there are documents that Impax is withholding. Specifically, we asked wither Impax actually considered any alternate extended release venlafaxine formulations or the development of a generic immediate release venlafaxine formulation prior to the filing of ANDA No. 78-057. You were unable to represent that such consideration did not occur or identify whether Impax was withholding such documents.

With respect to Impax's General Objections 9-10 and 12 to Wyeth's document requests and Wyeth's interrogatories you indicated that Impax simply indicated that it did not agree to anything beyond what was required by the Federal Rules. You further stated that Impax had indicated in its responses the particular categories of documents

<sup>&</sup>lt;sup>1</sup> For example, you indicated that Impax would withhold a non-privileged document in which a scientist involved in the development of the accused infringing product had reviewed and commented upon the patents-in-suit.

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that it would agree to produce. I responded by pointing out that Impax already had a General Objection to that effect (Impax General Objection No. 1), and that therefore to the extent that this is all that was intended, General Objections 9-10 and 12 to Wyeth's document requests and Wyeth's interrogatories are duplicative and unnecessary. Nevertheless, you indicated that Impax would not withdraw those General Objections in response to my request. You further were unable to represent whether Impax is withholding any documents based upon those general objections in addition to documents relating to products not the subject of ANDA 78-057 or documents relating to the patents-in-suit. You also were unable to represent whether Impax was withholding any documents on the basis of its objections as "unduly burdensome" or "oppressive." If Impax does not withdraw these objections or represent that it is not withholding any documents (other than those listed above) based on these objections, we will be forced to seek assistance from the Court.

You represented that Impax is not withholding any documents on the basis of Impax's "vague and ambiguous" objections. Instead, you indicated that Impax is attempting to interpret Wyeth's document requests to the best of its ability and produce the documents in accordance with its understanding. Specifically, we understood that this representation applies to at least the following requests:

- Wyeth Document Request No. 5 on the basis of its objection that the term "that resulted in" is vague and ambiguous;
- Wyeth Document Request Nos. 6-9 on the basis of its objection that the term "in vitro dissolution testing" is vague and ambiguous;
- Wyeth Document Request No. 16 on the basis of its objection that the terms "analysis," "study," "investigation," "testing," and "report" are vague and ambiguous;
- Wyeth Document Request No. 17 on the basis of its objection that the terms "materials," "process used to manufacture," and "market" are vague and ambiguous;
- Wyeth Document Request Nos. 26-27 on the basis of its objection that the terms "market," and "decision to market" are vague and ambiguous;
- Wyeth Document Request Nos. 32-33 on the basis of its objection that the terms "studies," "reports," "opinions," "conferences," "interviews," and "analyses" are vague and ambiguous;

Filed 09/18/2006

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- Wyeth Document Request No. 47 on the basis of its objection that the terms "adverse events," "Immediate release," and "immediate release formulation of venlafaxine," are vague and ambiguous;
- Wyeth Document Request No. 56 on the basis of its objection that the term "plans for promoting or encouraging the sale and use" is vague and ambiguous;
- Wyeth Document Request No. 57 on the basis of its objection that the terms "procedures," "protocols," "strategies," and "generic" are vague and ambiguous;
- Wyeth Document Request No. 59 on the basis of its objection that the terms "press release," "publicity release," "trade release," and "notice to trade" are vague and ambiguous;
- Wyeth Document Request No. 62 on the basis of its objection that the terms "encourage" and "switch" are vague and ambiguous;
- Wyeth Document Request No. 63 on the basis of its objection that the terms "promotion" and "substitute" are vague and ambiguous;
- Wyeth Document Request No. 69 on the basis of its objection that the terms "market," "market analysis," "financial models," and "surveys" are vague and ambiguous;
- Wyeth Document Request No. 70 on the basis of its objection that the term "demand" is vague and ambiguous;
- Wyeth Document Request No. 71 on the basis of its objection that the term "projected market share" is vague and ambiguous;
- Wyeth Document Request No. 72 on the basis of its objection that the terms "potential market" and "potential sales" are vague and ambiguous;
- Wyeth Document Request No. 73 on the basis of its objection that the terms "public statements," "press releases," "publications," "generic," "branded," and "relationship" are vague and ambiguous;
- Wyeth Document Request No. 74 on the basis of its objection that the term "marketing" is vague and ambiguous;
- Wyeth Document Request No. 75 on the basis of its objection that the terms "consultations" and "analysis" are vague and ambiguous; and

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• Wyeth Document Request Nos. 84-85 on the basis of its objection that the term "considered" is vague and ambiguous.

With respect to Impax's objection to Wyeth Document Request No. 80 "because the documents sought are publicly available and can be directly obtained from the third parties," you indicated that you would endeavor to get back to me today on whether Impax would produce copies of the requested documents to the extent they exist in Impax's files. You further indicated that in response to other Wyeth document requests that Impax was not excluding from its production responsive documents located in its files on the basis that they are publicly available.

Finally, you represented that Impax would not withhold non-privileged documents concerning Impax's bases for its Paragraph IV certification.

I agreed to clarify whether the term "data compilations" in Wyeth's General Objection No. 15 to Impax's second set of document requests referred to listings of raw data or included analysis.

Many of Wyeth's concerns with Impax's discovery responses have been pending for over a month and the parties have reached an impasse. If you disagree in any respect with this recitation of the meet and confer, please let me know immediately.

Sincerely,

Linda A. Wadler

LAW/amn

Mary B. Matterer, Esq. (via Facsimile) cc: Richard K. Herrmann, Esq. (via Facsimile)

# EXHIBIT 6

## HellerEhrmanu

September 13, 2006

VIA EMAIL TRANSMISSION

Jessica R. Wolff, Shareholder jessica wolff@hellerehrman.com Direct +1.858.450.5846 Main +1.858.450.8400 Fax +1.858.450.8499

38460.0011

Linda A. Wadler, Esq.
Finnegan Henderson Farabow Garrett
& Dunner LLP
901 New York Avenue, N.W.
Washington, D.C. 20001-4413

Re: Wyeth v. Impax Laboratories, Inc.

U.S. District Court, District of Delaware

Civil Action No. 06-222

Dear Linda:

The purpose of this letter is to follow up on our meet and confer of Friday, September 8, 2006. As I indicated in the call, we will endeavor to provide comments this week to your voluminous changes to the proposed Protective Order.

You also requested that I inform you whether Impax was withholding any documents in response to particular Requests for Production, due to Impax's objection that the request was overly broad and unduly burdensome. As indicated in our Response to Wyeth's First Request for Production of Documents and Things (Nos. 1-87), Impax will not search for and produce documents in response to Requests for Production Numbers 57, 67, 73, and 81, which are grossly overly broad and unduly burdensome. Furthermore, regarding Request No. 81, to the extent that Impax has materials from third parties such as IMS, it is likely that Wyeth already has this information. In addition, we are informed that third parties, like IMS, contractually prevent Impax from sharing this information.

We note that Wyeth has also raised general objections without specifying whether it has withheld documents and if so, which documents it has withheld based on these general objections. See, e.g., Wyeth's general objections 1, 15-17, and Mr. Ernst's letter of September 7, 2006. Please verify that Wyeth is not withholding documents based on its general objections as Wyeth has demanded of Impax.

Although you are unable to articulate how the documents requested by Request No. 80 are relevant to the instant lawsuit and you can easily obtain them from public records, in the

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Linda A. Wadler, Esq. September 13, 2006 Page 2

spirit of cooperation Impax will be producing non-privileged documents in response to this request.

You also asked me to inform you whether Impax worked on an immediate release venlafaxine product. I am informed by Impax that it did not. Moreover, as I reiterated in our conversation, Impax will not produce documents in Impax's possession concerning an extended release venlafaxine formulation that do not relate to Impax's ANDA 78-057 product. This is the only product that allegedly infringes Wyeth's patent claims. Any documents on other formulations are not relevant to Wyeth's allegations of infringement. Impax stands by its objection to producing documents that do not relate to Impax's ANDA 78-057 product.

I can confirm that Impax will produce non-privileged responsive documents on Impax's research and development of the ANDA 78-057 product, such as *in vitro* dissolution studies.

As explained in detail in previous letters and as I discussed in the call, Wyeth has withdrawn its claim for willfulness and thus discovery on willfulness and exceptional case issues, including documents showing an awareness of the patents-in-suit, is not proper. We have provided case law to you on this subject. Your argument that you need non-privileged documents showing Impax's awareness of the patents-in-suit to prove copying and infringement under the doctrine of equivalents is disingenuous. The strongest evidence on whether there is copying is a comparison of the two formulations. Such comparison makes clear that Impax's formulation is not a copy of Wyeth's patented formulation with a microcrystalline cellulose drug matrix. While we believe that Wyeth is completely foreclosed from arguing infringement under the doctrine of equivalents, assuming it is not, Wyeth will have to prove infringement under the doctrine of equivalents through proof that aspects of Impax's formulation perform substantially the same function in substantially the same way to achieve substantially the same result as the missing microcrystalline cellulose. Such evidence will not come from an awareness of the patents-in-suit.

Contrary to your assertions in your letter, I did inform you that Impax was relying on the withdrawal of Wyeth's willfulness claim for withholding documents. In addition, I did inform you that Impax was continuing to rely on its objections as stated in its Response to Plaintiff's Requests for Production (Numbers 1-87).

I also can confirm that Impax intends to begin producing documents or making them available for inspection before October 10, 2006. Unlike Wyeth, Impax does not have the

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Linda A. Wadler, Esq. September 13, 2006 Page 3

benefit of having gathered and previously produced some of the responsive documents in previous litigations.

By the end of this week, we look forward to receiving Wyeth's responses concerning:

- 1) Our proposal limiting the discoverability of attorney-expert communications; and
- 2) The meaning of clinical "data compilations" in your general objections to Impax's Second Request for Production of Documents (See Number 15).

Sincerely,

Jessien R. Wolff Jessiea R. Wolff

ce: Mary Matterer, Esq. Sam Ernst, Esq.

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